

Structured Product Labeling (SPL) OTC Sub-team Teleconference

Monday, November 10, 2008, 1:00 pm – 2:00 pm ET

Minutes

I. Welcome and Introductions - call participants (listed alphabetically):

- David Brown, Colgate Palmolive Company
- Shelia Dy Juanco, Medline Industries, Inc.
- David Grob, Chattem, Inc.
- Chris Guay, The Procter & Gamble Company
- Maureen Kapustynski, Cadbury
- Jeffrey Karp, Geronmed, Inc.
- Mike Koenig, U.S. Food and Drug Administration
- Juris Lazdins Novartis Consumer Health, Inc.
- John Lorenc, Reed Technology and Information Services, Inc.
- Kathryn Moreng, Bayer Consumer HealthCare
- Devon Morgan, Perrigo Company (co-leader)
- Priscilla Mott, Johnson & Johnson Consumer & Personal Products Worldwide
- Kathy Olgers, Perrigo Company
- Janet Riffitts, McNeil Consumer Healthcare
- Nick Romano, Novartis Consumer Health, Inc.
- David Schilling, Chattem, Inc.
- Barbara Spallitta, Reckitt Benckiser, Inc.
- Siobhan Stevens-Miles, Merck & Co., Inc.
- Carl Strotz, Wyeth Consumer Healthcare
- Craig Trautman, Intagras
- Mark Vranich, Blistex, Inc.
- Ann Vu, U.S. Food and Drug Administration

- Barbara Wolfe, Wyeth Consumer Healthcare
- Marcia Howard, CHPA staff (sub-team liaison)

II. Standing Teleconference Date and Time

The next teleconference will be November 24, 2008, at 1:00 pm ET unless cancelled.

III. Update on DIA SPL Workshop

The DIA SPL workshop was a successful event. All slide presentations received from DIA will be posted to the Wiki website as soon as the material becomes available (if permission to do so is granted by DIA). Slides from the GPhA meeting held on October 28, 2008, are currently available on the Wiki page and may contain similar information as some of the speakers were the same for both meetings.

IV. Proposal to Host Vendor Presentations




There was agreement that it would be beneficial to have the various vendors conduct webinar presentations on services and products available to companies during our regularly scheduled calls. Because FDA sub-team members cannot be present for these types of presentations, routine business will be conducted during the first part of the bimonthly calls followed by the vendor presentations. This educational forum is open to all vendors, including vendors who were present at the DIA meeting but may not be members of the SPL OTC sub-team. **Any vendor interested in making a presentation to the sub-team should contact Marcia Howard via email.**

There was also a request to invite a Dun & Bradstreet representative to speak to the sub-team which Howard will attempt to arrange.

V. Feedback on the October 23, 2008, *Federal Register* notice

There was discussion about the October 23, 2008, *Federal Register* (FR) notice issued by FDA on its information collection activities submitted to the Office of Management and Budget (OMB). Please see <http://www.fda.gov/OHRMS/DOCKETS/98fr/E8-25338.pdf> for complete details

about the issue. It was noted that the reporting and recordkeeping burdens reported in the *FR* notice appear to be reasonably accurate but may not account for or accurately estimate set-up time and resources. Because any response to FDA will require facts and figures to be useful to the agency, general comments on behalf of the sub-team will only be submitted if individual companies can and will provide at least top-line data to Paula Markert, Devon Morgan, and Howard by Monday, November 17th. Companies are asked to notify the co-leaders and Howard by 5:00 pm ET on Tuesday, November 11th if they plan to submit information for inclusion into general comments. (Unless additional information is obtained from individual companies, general comments are unlikely to be meaningful and may not be submitted.) These deadlines are necessary in order to allow sufficient review time by sub-team members prior to the November 24, 2008, submission deadline. If general comments are submitted, the key elements of the submission will be:

-  Estimation of time and resources for set-up
-  Oversimplification of the use of the Electronic Submission Gateway (ESG)
-  Estimation of time and resources for creation of the Content of Labeling necessary for OTC electronic submissions

Individual companies are encouraged to submit comments as deemed necessary regardless of the decision whether or not to submit general comments on behalf of the sub-team.

VI. Educational Opportunities

Anyone who has or is sponsoring educational forums on SPL with open participation should notify Markert, Morgan, and Howard so the information can be shared with sub-team members. Only one educational opportunity is known to be scheduled within the next two weeks. Reed Technology will host an audio conference in Tuesday (11/11) and Thursday (11/13).

Reed Technology Audio Conference

Tuesday (11/11) or Thursday (11/13); 1:00 – 2:30 pm ET

Pre-registration required: [Ben McGinty](#)

VII. Next Steps and Assignments

- A. By 5:00 pm ET Tuesday, November 11, sub-team members will inform Markert, Morgan, and Howard if they will have data to provide by Monday, November 17 for incorporation into general sub-team comments.
- B. Marcia Howard (CHPA) will post DIA presentations when they become available.
- C. Marcia Howard will work with vendors and Dun & Bradstreet for future presentations to the sub-team.
- D. Vendors interested in presenting a webinar to sub-team members during a future teleconference should contact Marcia Howard via email

MDH/11-10-08

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Last Revised: November 10, 2008 Sent: November 6, 2008